

Serial No.: 09/682,161
Group Art Unit No.: 3626

Amendments to the Claims:

1. (Original) A registration and sample ordering system for the blinded, randomized testing of samples of a product at one or more sites, the system comprising:
 - i) a remotely accessible electronic database programmed to:
 - a) run real-time or batch data processes,
 - b) process at least two call flows,
 - c) receive and process test subject registration data,
 - d) randomize subjects, and
 - e) determine when study numbers are fulfilled and thereafter lock out additional subjects;
 - ii) said database being linked to an interactive electronic ordering and tracking system for supplying samples to one or more sites, said ordering system having an electronic randomizing operation for randomizing and individualizing samples based on prior subject randomization.
2. – 8. (Cancelled)
9. (Newly added) A system according to claim 1 wherein the interactive electronic ordering and tracking system incorporates voice recognition technology for placing orders.
10. (Newly added) A system according to claim 1 wherein the electronic randomizing operation provides a virtual randomization system integrated with the electronic supply and shipping of samples.
11. (Newly added) A system according to claim 1 which is based on six different fixed flows comprising registration, open label, run-in, double blind, stratified and titration.
12. (Newly added) A system according to claim 1 that locks out additional enrollments when enrollment targets are reached.

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13. (Newly added) A system according to claim 1 which ensures sites are approved for use, cuts off non-compliant sites, monitors site documentation and ensures appropriate filings have been made in all participating countries.